

SCIENTIFIC MISCONDUCT: ROLE OF THE RESEARCH COORDINATOR

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Purpose: Research Coordinators (RCs) hold a unique position in clinical trials management and can be expected to be aware of and even influence the scientific integrity with which the research is implemented and the findings disseminated. The purpose of this study was to conduct a national survey of clinical research coordinators in order to describe their beliefs, attitudes about and experiences with SM. Method: The Scientific Misconduct Questionnaire-revised (SMQ-R) was sent to 1000 research coordinators who are members of the Association of Clinical Research Professionals. The SMQ-R asks respondents to a) describe their perceptions and beliefs about SM and the factors in their institution that influence it, and b) the prevalence of any actual misconduct that occurred and if they reported it as well as what happened if, or when, they reported it. RCs who were aware of an actual incident of SM responded to 8 open-ended questions and described their experiences. To date, 256 eligible RCs completed the SMQ-R, 54(21.1%) indicated awareness of SM occurrences within the last year and 56 described an actual occurrence. The majority of the respondents were female (96.9%), Caucasian (92.2%), RNs (64.7%) and certified in clinical research (82.4%), with an average age of 45.15 (sd=8.84). The mean number of studies for which RCs were responsible for enrolling subjects was 5.18 (sd=5.42), while the mean number of studies for which respondents were responsible for following (but not enrolling) subjects was 6.95 (sd=8.63). Findings: The most prevalent SM types reported were violations of protocols for procedures (84.4%) and subject enrollment (74.5%), but most described the frequency of these violations as seldom. Only 52 (20.3%) indicated that coercion of potential subjects occurred. One-fourth (24.6%) indicated that pressure from sponsors to engage in unethical practices occurred; 44.7% indicated that they were concerned about the amount of SM. RCs believed chances for getting caught for SM were high (73.0%) and penalties would be severe (77.3%). Two-thirds (67.6%) indicated that if someone engaged in SM and was reported at their institution, then they were very likely to be disciplined; however, 12.1% indicated that the likelihood of discipline would depend on the person's position (investigator or staff). When asked what a typical RC would do if they were aware that a PI or co-investigator violated rules for research integrity, 9.6% indicated a typical RC would do nothing, 33.1% indicated they would express disapproval to the PI but not report it, 29.5% indicated they would ask the investigator to report themselves and report them if they did not, and 27.9% indicated that a typical RC would report the PI to appropriate authorities. The frequencies of responses to this item for subjects who did or did not have first-hand knowledge of a specific instance of SM in the past year were not significantly different (chi-square=4.462, p=.216). At least 25% of respondents identified the following as strong influences on SM: funding pressures, need for recognition, need for publication, insufficient involvement or low interest of PI, and intensity of protocols for which RC was responsible. The number of protocols for which the RC was responsible was described as having some influence by 57.1% and a strong influence by 24.2% of respondents.